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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,525	03/30/2001	Stephanie McKeown	A-70409/RFT	1147

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EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,525	MCKEOWN ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,10,11 and 13-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,10,11 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Re: McKeown *et al.*

Date of priority: 09/30/1998

Response to Amendment

The Amendment filed November 24, 2003 in response to the Office Action of June 24, 2003 is acknowledged and has been entered.

Claims 13-19 were added.

Claims 2, 4, 10-11, and 13-19 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 2 and 10 remain rejected and claims 4, 11 and 13-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the diagnosis of first presentation or recurrence of bladder cancer, a method for diagnosing a urinary infection, or assessing genitourinary health of a patient, consisting of detecting a 37kDa fragment of epidermal growth factor receptor (EGFR) in a urine sample wherein the presence of the fragment is detected using antibody Ab4, does not reasonably provide enablement for the method as broadly claimed for the reasons of record in the Action mailed June 24, 2003 (pages 4-6).

Note: The previous Action did not include Claim 11 in the 112, 1st paragraph rejection because it had not been further treated on the merits (page 2). Accordingly, since applicant has appropriately amended Claim 11, it is now properly incorporated into the present rejection.

Applicants argue (page 9) that amended Claims 2 and 10 recite that the 37 kDa fragment is detected by an antibody that specifically binds the 37 kDa fragment. Applicants further submit that methods of making antibodies to particular protein or fragments of proteins, are well known. Additionally, applicants argue that amended Claims 4 and new Claim 13 recite that such an antibody can be one that is raised against a peptide corresponding to amino acid residues 1005 to 1016 of EGFR. These arguments have been carefully considered but are not found persuasive. Independent claims 2, 10, 15 are broadly drawn to detecting the presence of any 37 kDa fragment of EGFR by specifically employing any antibody. And, as set forth previously, applicants have not taught how one of ordinary skill in the art would be able to produce antibodies which would predictably and specifically recognize an epitope of EGFR that would immunoprecipitate the same 37 kDa fragment as applicants with the same diagnostic qualities. There is insufficient guidance and direction to one of skill in the art to predictably diagnose bladder cancer (or a urinary infection) by including all antibodies that may or may not immunoprecipitate a diagnostic fragment of EGFR that is 37 kDa. Further, with regards to antibodies raised against a peptide corresponding to amino acid residues 1005 to 1016 of EGFR, the disclosure fails to provide a nexus between these specific residues and the target 37 kDa fragment. In other words, it is unclear if an antibody raised against these residues would predictably bind to a 37 kDa EGFR fragment because the disclosure fails to teach the relevance

of these residues to the claimed invention. Thus, the only particular preferred embodiment of antibodies that predictably, specifically bind to the "diagnostic" 37 kDa EGFR fragment is the Ab4 antibody as set forth in the specification on page 5, line 24. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

New Rejections:

Claims 4, 13, 17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims attempt to limit determining the presence of the 37 kDa EGFR fragment by using an antibody raised against a peptide corresponding to amino acid residues 1005 to 1016 of EGFR. However, the claims are vague and indefinite because there is no frame of reference for determining the composition or chemical make-up of these amino acid positions in EGFR. The disclosure does not teach any amino acid sequence associated with the claimed EGFR nor which particular amino acid residue begins at position 1005 and or ends at position 1016. Thus, the claims do not particularly point out nor distinctly claim the subject matter that applicants regard as the invention, and the metes and bounds of the claims cannot be determined.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Examiner
Art Unit 1642

GBN

Gary B. Nickol